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A Crucible for Generic AIDS Medicines --- Tests of Drugs in Nigeria, India May Well Shape The Destiny of Millions

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NEW DELHI -- Generic AIDS drugs, which have stirred controversy even while offering a potent new weapon in the battle against the disease in poor countries, will soon face several key field tests in Africa and India.

Nigeria, Africa's most populous country, this week announced a plan to use cheap generic drugs starting in September to treat as many as 15,000 people. A smaller project in India is also about to launch, targeting a crucial population of migrant laborers in the most remote desert villages, and Kenya recently passed a law opening the door to production of generic AIDS drugs.

Bombay-based drug maker Cipla Ltd., whose low pricing was a catalyst for the burst of activity surrounding generic AIDS drugs, says that in the past few months at least 20 countries, from Cameroon to Jamaica to Iran, have either purchased or said they plan to purchase its AIDS generics.

The price of AIDS drugs has been a prime obstacle in fighting the fatal immunological disease. These early programs will provide the first clues about how helpful the cheaper drugs will be in making inroads against AIDS in countries that have been hardest hit. Africa is home to roughly 70% of the world's individuals infected with HIV, the virus that causes AIDS.

Still, administrators of these programs are quick to acknowledge the difficulties of treating the disease, even with cheap drugs. "In the field, a lot of things come up that you never thought would be there," says Alejandro Haag, medical director at the Association Francois-Xavier Bagnoud (FXB), a Swiss group running programs in India and Uganda. One big problem is getting patients to adhere to the required regimen of pill-taking. AIDS drugs must be taken several times each day, for life. Some worry that resistant strains of HIV could develop if patients are lax and supervision breaks down in far-flung and impoverished settings.

Cipla stirred up controversy earlier this year when it offered to sell a "cocktail" of AIDS drugs for as low as $350 per patient per year, more than 90% less than previous list prices among Western drug makers. That made up-to-date treatments possible in developing countries.

It also stoked fears among Western drug companies that they could lose valuable patent rights. (India doesn't recognize international patent laws, allowing Cipla and other Indian manufacturers to legally make knockoffs of drugs still under protection elsewhere.)

Nigeria's program will push the issue of access to medicines further into the public eye, especially after the leaders of the Group of Eight leading countries took up the cause of Africa at their recent meeting in Genoa, Italy.

Nigeria's plan will provide drugs to only about 15,000 people. That is a tiny group, considering Africa has roughly 25 million people infected continent-wide. Nigeria alone has 2.7 million people infected, according to the most recent United Nations estimates.

But it is likely to encourage other African countries to follow suit. One in every seven Africans is Nigerian, and the country wields tremendous influence on the continent. Pressure will increase on South Africa, for example, to devise a similar plan. Despite one of Africa's worst AIDS problems, South Africa has delayed the

use of antiretroviral drugs in the private sector, and officials, including President Thabo Mbeki, have at times questioned their effectiveness.

In Nigeria, drugs will be administered at 17 sites. Patients will be charged $7 to $8 a month for the treatment. That represents a change from Cipla's initial cheap-drugs offer, which originally stipulated that patients wouldn't be charged for the medication. However, Nigeria negotiated a special deal under which the state subsidizes about 80% of the cost to the patient.

The India program organized by FXB is more modest in scale, with a goal of treating 400 patients. However, about 200 will be in remote desert villages, where many migrant workers have returned from big-city jobs with HIV. Isolation of the villages makes it almost impossible for clinics to achieve "directly observed treatment," the preferred method for making sure a medical regimen is adhered to. In its place, the organization is training family members and the village community to take responsibility for seeing that patients stick to their treatment.

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